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	Research Triangle Park NC 27709								9. DESTINATION							
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				ANT: This is a request for information, and quotations furnished are not												
OR BEFORE	ed in the preparation	on this form and return it to the address in Block Sa. This request does not commit the G in the preparation of the submission of this quotation or to contract for supplies or service less otherwise indicated by quoter. Any representations and/or certifications attached to							domestic							
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ITEM NO.	Region V RARE Project: An Epidemiologic Study of Manganese Exposure in East Live Ohio					erpool,			ı	INIT PRICE		AMOUNT (f)				
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> 8371 Kent Drive > El Cerrico, CA 94530 > Tel: 510.236.5599, FAX: 510.236.3370, cell 510.290.1065 > Gundages (Magagasada) (Cell 510.290.1065)

One toenail sample (maximum of 100 samples for this study)

One hair sample (maximum of 100 samples for this study)

A set of results from standardized neurological tests such as UPDRS, CATSYS, Cognitive, Motor and Tremor, and Mood.

The contractor shall process, store, and ship all biological samples using procedures in the EPA approved Study Plan. Due to the high visibility of this study, the EPA may require a Technical Systems Review (TSR, QA audit) of this study. The contractor shall be prepared to be QA audited by the EPA. The contractor shall ship the whole blood to the same laboratory used in the Marietta study for the analysis of a metals panel which includes Mn. The contractor shall ship nail and hair samples to the approved location for Mn content analysis. The contractor shall ship the serum samples to an EPA point of contact, to be named after the award of this contract, for subsequent Ferritin and liver enzymes analyses. The contractor shall be responsible for the disposal of all materials used during the sample processing or analysis work. The contractor shall ship any unused sample to the EPA upon completion of the analysis work.

Analyses/Reports/Manuscripts: The contractor shall analyze the data from this study according to the approved data analysis plan. The contractor shall write the following:

- 1. An Interim Report which describes the conduct of the field collection of information and samples. A draft of this report shall be due within 30 calendar days of the completion of the field study. The EPA will review and provide comment on this report within 15 calendar days. The contractor shall incorporate any EPA comments and provide a final version of this report no more than 15 calendar days after the receipt of the EPA's comments.
- 2. A Final Report which details the data analysis results and contains all biological sample laboratory analysis results. A draft of this report shall be due within 7 months of the completion of the field study. The EPA will review and provide comment on this report within 21 calendar days. The contractor shall incorporate any EPA comments and provide a final version of this report no more than 30 calendar days after the receipt of the EPA's comments.
- 3. A journal article suitable for submission to a peer-reviewed journal such as Environmental Health Perspectives or Neurotoxicology. The contractor shall prepare a draft for comment by the EPA within one month of the EPA's acceptance of the Final Report. The EPA will provide comments on the draft within 21 calendar days of receipt. The Contractor shall incorporate any EPA comments, clear the article through the EPA Clearance Process and submit the article to the specified Journal. The Contractor shall be responsible for incorporating reviewer comments and for all publication charges.

D. Government Responsibilities

The government researchers will be responsible for obtaining approval for the study from the EPA IRB of record, the University of North Carolina Institutional Review Board, and EPA Human Subjects Approval. The government researchers will provide templates for QAPP, Study Plan and IRB submission materials within 14 days of award of this contract. The government researchers will provide estimates of air Mn levels in East Liverpool, OH for the study time period. If the EPA requires a Technical Systems Review of this study, the government researchers will provide a copy of the TSR final report. The government researchers will perform the serum Ferritin and liver enzymes analyses and provide the results to the contractor within 6 months of sample receipt. The government researchers will provide comments on the Interim Report within 15 calendar days of receipt, will provide comments on the journal article within 21 calendar days of receipt.